

These are a Few of Our Favorite Things – Current Thoughts on Design and Innovations in Consumer Research

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Disclaimer

Views expressed are those of the speaker and may not represent positions of FDA, the Center for Drug Evaluation and Research, the Office of New Drugs, or the Division of Nonprescription Drug Products. Title reference with apologies to Rogers, Hammerstein, Mary Martin, John Coltrane, Julie Andrews, The Supremes, Herb Alpert, Carrie Underwood, Kelly Clarkson, and various others.

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OTC Application Consumer Studies: Observations about Design

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Refresher

- Means to demonstrate that consumers can use the drug product in a safe and effective manner
- Overall goals
 - the label effectively communicates risk and safe use
 - consumers make the right choice about their use of the product based on the label
 - safe use of the product under normal conditions of use
 - use of a product (device) based on instructions

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OTC Consumer Studies

Label Comprehension Study

- Understanding the key label messages

Self- Selection Study

- Making the right choice about the product

Actual Use Study

- Using according to labeled directions

Human Factors Study

- Interacting with the product

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Label Comprehension – Typical Design

- Open-label, uncontrolled tests; not trials
- Assess content, access, and comprehension
- Establish primary communications objectives based on key labeling elements
- Present scenario questions that address these communications objectives
- Set *a priori* target thresholds that reflect medical consequence/risk considerations
 - Target thresholds for pivotal study are a pre-specified proportion reflecting clinical rationale
 - Outcomes are not viewed the same as traditional clinical trial success thresholds

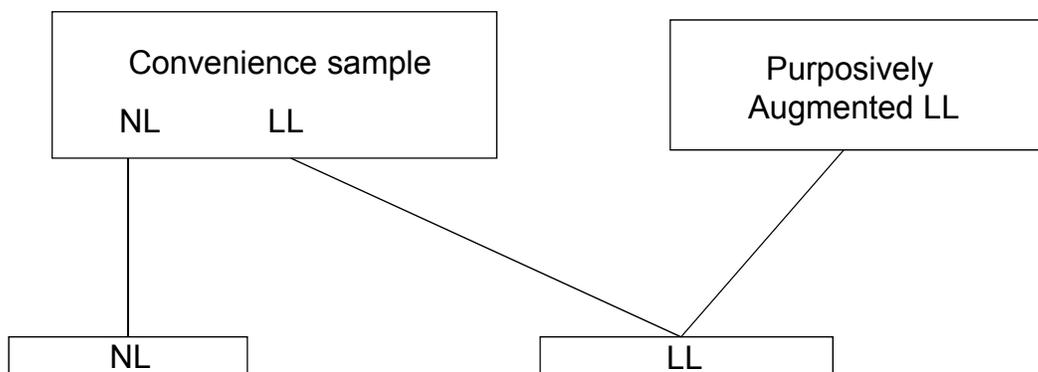
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Outcome Hierarchy	Message	Scenario Question	All Combined (n=542)	Literacy ≥ 60 (n=416)	Low Literacy (n=126)
Primary	Dangerous DDI with a class of drugs —it is an absolute contraindication	Bob takes (a type of contraindicated drug) and wants to use (your product). What does the label say he should do?	82% (78%, 85%)	88% (84%, 91%)	63% (54%, 71%)

Typical LCS Design and Analyses

Cohort 1 – Emphasis on threshold

Cohort 2 – Insights into LL



Our Favorite Things

- Representativeness of health literacy
- Iterative testing; pilots
- Open-ended response framing
- Unique testing of elements in composite messages (e.g., pregnancy and breastfeeding)
- Recognizing sequential nature of studies beginning with LCS
- Significance of key safety and use messages across the suite of studies
- Your willingness to test novel items and re-test significant warnings and instructions in the context of new labels

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Self-Selection—Typical Design

- A higher-stakes label comprehension test
- Individual endpoint is the consumer's determination if use of the drug is appropriate for them based on label considerations, evaluated as correct or incorrect
- After reading the label, the consumer is asked if the product is right for them. This is usually followed by a probe asking why or why not.

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Self-Selection Test

- Success of a drug application can depend on ability of consumers to self-select
- High importance for first-in-class applications in OTC drug world



Larson—fair use

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Self-Selection Design (cont.)

- “All comers” sampling—generally like label comprehension—BUT targeted groups or population may be appropriate for ‘enrichment’
- Outcome of interest is the proportion with appropriate self-selection (OFTEN “deselection”—making an appropriate choice to not use the product)
- Additional information needed (e.g., medical history, list of current medications) to determine accuracy of choice

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Getting the Outcomes Right



Appropriateness of product for consumer based on labeled safety and use information, considering consumer's characteristics

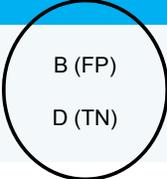
Consumer's Selection	Appropriate	Inappropriate
Yes, OK for me	A (TP)	B (FP)
No, not OK	C (FN)	D (TN)

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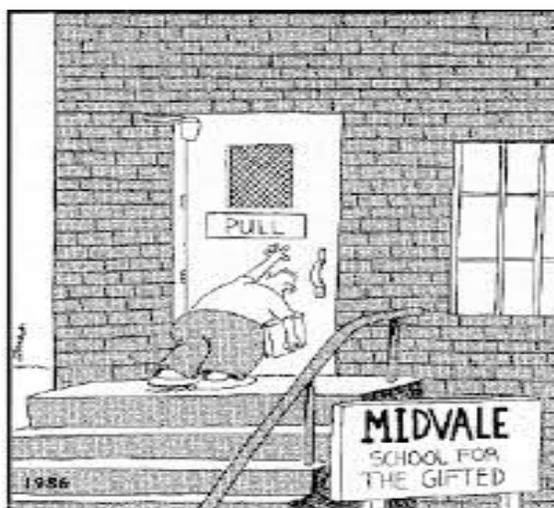


Our Favorite Things

- Asking the right question, leading to the right outcomes (with justified thresholds)
- An optimal sample (with representative health literacy)
- Dichotomous framing with open-ended justification
- Significant safety and use messages embedded in the selection decision, especially contraindications
- Separate SSS and AUS studies, particularly when the goals differ widely and self-selection is high stakes

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The Actual Use Study



Larson—fair use

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Actual Use Studies — Typical Design

- Categorized as consumer studies, they are by definition clinical studies involving a drug
- Most often a self-reported, open-label of study of safe use
- Data collection relies on diary methods
- Individual outcomes most often instances of inappropriate use while measures of interest may be rates or proportions of misuse
- Recent requests for application of behavioral trials—move from observational cohort to RCT

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Our Favorite Things

- “Enriched” samples guaranteeing regular use during study (representativeness including health literacy)
- Justified, negotiated endpoints with pre-specified thresholds
- Electronic diaries
- Ongoing recording of significant safety concerns (esp. concomitant medications)
- Follow-through on key safety and use messages tested earlier in LCS and SSS outcomes

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One More Very Favorite Thing...

- Exploration of consumers' explanations of why failures (usually misuse) occur

Applicable both to self-selection and actual use, this is a key way we can keep discussion open for finding a path forward!

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Methods, Materials, and Data

- Recruitment materials
- Screening scripts
- Transparent information on “mitigations”
- Inclusion of “verbatim” information in datasets
- Preliminary sample datasets for feedback on the dataset structure

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Consumer Studies and Regulatory Science:

Thursday and Beyond

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Innovative and Diverse Methods for Understanding Consumer Behavior

- Shiffman, Bix and Richardson presentations were indeed innovative and diverse
- The application of diverse methodologies for triangulating on any number of questions is promising
- Application of mixed methods in new and creative ways will advance our understanding
- Won't for the moment substitute what we ask for, but we welcome studies to the extent they inform regulatory concerns

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Consumer Navigation and Selection Behaviors Study

- Very informative marketing survey by Aker and colleagues for CHPA
- Focus on key role of brand in identification and trust
- Internet survey (N=204)
- Results
 - brands useful in navigation
 - hierarchy of choice: symptoms, brand, price
 - perception of effectiveness as core of repeated brand use
- Findings not having impact for regulatory concerns, as they address marketing questions

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Internet Surveys in General

- Potentially useful adjuncts—not a replacement for—the usual consumer studies
 - Assuming they ask questions of regulatory concern
 - Assuming sampling is transparent and sufficiently representative for findings to have meaning
- Potentially informative tool for surveys about safe use and a range of relevant issues

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Internet Surveys (cont.)

- Well-recognized limitations or challenges
 - Selection bias due to volunteer sampling and digital divides
 - Pre-coded responses where open-ended responses may be desirable
 - Greater chance for respondent misrepresentation (e.g., age)
- Exploratory and descriptive studies with informative content that we would not typically evaluate

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Table 1. Comparison of study respondents with U.S. Census

	Total initial recruits (n=18 533)		Final sample (n=5,649)		U.S. Census (2009 projections)
	No.	%	No.	%	%
Age (median)		44		49	47
Male	8057	43	2481	44	49
White race	14 465	78	4613	82	77
Education*					
<12 years	389	3	139	2	15
HS graduate	2110	15	877	16	28
Some college	5256	37	2001	36	29
College graduate	6572	46	2610	46	28
Income* [†]					
<\$25 000	2878	17	824	16	25
\$25 000–49 999	4537	27	1412	27	25
\$50 000–74 999	3762	22	1215	23	18
\$75 000–99 999	2736	16	828	16	12
≥\$100 000	3132	18	906	17	20
Region					
Northeast	3408	18	1129	20	18
Midwest	4664	25	1406	25	22
South	6563	35	2066	37	37
West	3898	21	1048	19	23

*Respondents with unknown education or income not included in the denominators.

[†]Household income.

Source: Kaufman DW, Kelly JP, Rohay JM, Malon MK, Weinstein RB, Shiffman S. (2012) Prevalence and correlates of exceeding the labeled maximum dose of acetaminophen among adults in a U.S.-based internet survey. *Pharmacoepidemiology and Drug Safety* 21:1280-88.

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Demographic characteristics

Characteristics	PROMIS, unweighted (N = 11,796)	PROMIS, weighted (N = 2.18 × 10 ⁶)	Census 2000, SF4 (N = 2.18 × 10 ⁸)	PROMIS: subsample (N = 2,196)
Age				
Mean (SD)	50 (18)	45 (17)	45 (18)	45 (17)
Age group (years), %				
18–29	16.9	22.5	22.5	22.4
30–44	24.1	31.8	31.8	31.9
45–59	25.9	24.1	24.1	24.1
60–74	18.9	13.8	13.8	13.8
75+	14.3	7.7	7.7	7.6
Gender, %				
Male	45.0	48.3	48.3	48.3
Female	55.0	51.7	51.7	51.7
Education, %				
Less than high school	2.8	20.3	20.3	2.5
High school diploma/GED	18.7	28.6	28.6	18.6
More than high school	78.5	51.0	51.0	78.9
Annual family income, %				
\$0–19,999	10.3	15.1	15.1	11.0
\$20,000–49,999	35.2	34.9	34.8	32.9
\$50,000–99,999	37.5	34.8	34.8	39.3
\$100,000 and higher	17.0	15.2	15.3	16.9

Source: Liu H, Cella D, Gershon R, Shen J, Morales LS, Riley W, Hays RD. (2010). Representativeness of the patient-reported outcomes measurement information system internet panel. *Journal of Clinical Epidemiology*. 63:1169-78.

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Eye-Tracking in General

- Broad appreciation of objectivity of technique
- Makes clear if information can be “seen”—objective measure of early processing and visual salience
- But basic concerns about inference
 - Duration or movement of gaze ≠ perception
 - Perception ≠ cognition
 - Cognition ≠ behavior
- Intelligent use within a broader menu of research methods seems best

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With FDA Input From

- Barbara Cohen
 - Jane Filie
 - Charles Ganley
 - Karen Higgins
 - Mona Khurana
 - Scott Komo
 - Theresa Michele
 - Ryan Rafaelli
- And past FDA experts on consumer studies